MAIL STOP APPEAL BRIEF-PATENT
PATENT
3003-1153

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Jeremy MARSHALL et al. Appeal No. _____

Serial No. 10/506,472 GROUP 3767

Filed April 6, 2005 Examiner A. Gilbert

MULTI-SPRING SUPPORT FOR NEEDLE SYRINGES

APPEAL BRIEF

MAY IT PLEASE YOUR HONORS: December 9, 2008

(i) **Real Party in Interest**

The real party in interest in this appeal is the current assignee, Owen Mumford Limited, of Oxford, United Kingdom.

(ii) **Related Appeals and Interferences**

None.

(iii) **Status of Claims**

The application contained claims 1-6 as originally filed.

By a preliminary amendment of September 3, 2004, claim 3 was amended, claims 5 and 6 were canceled, and claims 7 and 8 were added.

By an amendment of August 3, 2006, claim 1 was amended; and by an amendment of December 21, 2006, claim 1 was amended to its present form.

It is thus to the rejections of claims 1-4, 7 and 8, as they appear in the amendment of December 21, 2006, that this appeal is directed, these claims being the claims on appeal.

(iv) **Status of Amendments**

No amendment to the claims was filed subsequent to final rejection.

(v) **Summary of Claimed Subject Matter**

The claimed subject matter is a syringe by which a needle is first inserted in a patient, and then a liquid is injected into the patient through the needle.

It operates in two stages: in Figure 1, you see the cocked device before release. Upon release, the first spring 4 drives everything within the barrel 1 downward, together as a unit. The needle 3 thus penetrates the patient.

But first spring 4 is stronger than second spring 5, so when flange 12 fully compresses spring 11 against shoulder 13, the syringe 2 stops but the plunger 8 keeps going, which injects the liquid into the patient through the extended needle 3. It keeps going, because first spring 4 is stronger than second spring 5, and so spring 4 compresses spring 5 as the plunger 8 moves deeper into syringe 2 to inject the liquid.

Thus there is a two-stage action: first, everything within barrel 1 moves down in unison, which does nothing more than insert the needle 3 into the patient without dispensing any liquid. Then, in the second stage, the plunger 8 keeps going within the syringe 2, because strong first spring 4 overcomes weaker second spring 5, syringe 2 remaining stationary because

flange12 rests against spring 11, which is fully compressed against 13.

Next, for easier understanding of the claimed subject matter, we reproduce claim 1 hereafter, with appropriate reference numerals so that the claim can be easily read against the drawing.

> 1. An injection device having a housing with a spring drive operable, firstly to urge a syringe (2) within the housing forwards to a forward position to project its needle (3) from the forward end of the housing and then to press a piston within the syringe forwards to eject a dose through the needle, wherein the spring drive includes a first spring (4) that acts between the housing and a plunger aligned to cooperate with the piston to urge the plunger forwardly and a second spring (5) that acts in compression between the plunger and the syringe in opposition to the first spring (4) when the plunger presses said piston forwards to eject the dose, the second spring (5) being weaker than the first spring (4) but being sufficiently stiff to be in an expanded state when the syringe reaches its forward position with its needle (3) penetrating the flesh of a patient, whereupon the first spring (4), as it fully expands, will then compress the second spring (5) to urge the plunger forwards and thereby move the piston and expel the dose within the syringe, the second spring (5) meanwhile serving to retain the syringe seated at its forward position.

(vi) **Grounds of Rejection to be Reviewed on Appeal**

The two grounds of rejection to be reviewed on appeal are as follows:

1. The rejection of claim 1 under 35 USC §112, second paragraph as indefinite; and

2. The rejection of claims 1-4, 7 and 8 under 35 USC §102(b) as being anticipated by BERGENS et al., U.S. Patent 6,270,479.

(vii) **Argument**

Rejection under 35 U.S.C. §112, second paragraph

This rejection is apparently based on a misunderstanding on the part of the Examiner, as to which is the first spring and which is the second spring that we claim. The first spring is 4, the second spring is 5. As the plunger moves forward, second spring 5 is compressed. The force of spring 5 against collar 9 clearly holds the syringe seated in its forward position, as recited at the end of claim 1. We see no ambiguity nor need for amendment as to form.

The Examiner indicates that he is uncertain about the effect of the 'second spring" in main claim 9 of the present application. The second spring does act in opposition to the first spring "...when the plunger presses said piston forwards to eject the dose . As can be seen from figure 1 and the description in the paragraph bridging pages 3 and 4, the first spring (4) when active applies a downward thrust on the mushroom head (7) of the plunger, and the second spring (5) acts in opposition because it applies an upward thrust to the mushroom head (7), and so the springs act in opposition, but with the first spring prevailing.

Furthermore, the lower end of the second spring (5) engages the collar (9) and, as described in the sentence bridging pages 3 and 4, thrusts the syringe forwards (i.e. downward as seen in figure 1) via the collar (9). There is therefore a load path from the top end of the first

spring (which abuts the inner top surface of the housing (1)) to the mushroom head of the plunger and then through the second spring (5) to the collar (9) which, when the plunger is pressing the piston forward to expel the dose, is engaged with the syringe. In this manner, the second spring at its upper end is pushing against the mushroom head (7) and at its lower end is pushing, via the collar (9), the syringe flange (12) to retain it in its forward position. Thus the second spring applies a downward force via the collar and retains the syringe seated at its forward position.

The Examiner expresses uncertainty as to the phrase whereby said piston is not acted upon..." in relation to the final two lines of claim 9. However the meaning of this phrase is entirely clear when read in the context of the previous lines which states "...to urge the plunger forwards and thereby move the piston and expel a dose . It is clear that the action referred to is that of the plunger on the piston. We would particularly point out that the claim does not require the piston always to be in contact with the plunger, as suggested by the Examiner. As seen in Figure 1, there is a gap between the dotted lines indicating the lower ends of the plunger (8) and the dotted lines indicating the upper surface of the piston (14). In fact, the claim is not intended to limit to either contact or non-contact; the claim simply requires that the action on the piston to expel the dose is not applied until after the needle has penetrated. This is achieved by the presence of the second spring (5).

At the end of the §112 rejection, the Examiner recommends incorporating the recitation of the third spring 11, into the independent claim. But for the reasons given above, we do not

think this necessary. Note, however, that we separately argue the claims 3, 4, 7 and 8, directed to the third spring.

The Rejection Under 35 USC §102(b)

Claims 1 and 2.

We do not believe that the exact structure and operation of the device of BERGENS et al. can be determined from U.S. Patent 6,270,479.

In BERGENS et al. the Examiner relies on Figures 1A-1D, which show a form of mechanism for coupling and uncoupling a drive plunger or "injection head" 142 from the syringe plunger 126. The relevant elements of the device are a drive spring 140 which, upon release of a trigger drives a drive plunger 142 with a wine-glass-shaped head forward. The drive plunger transmits motion to a syringe 120 via a penetration head assembly 150. The main features seem to be a forward drive surface 152 which transmits forward movement to the syringe 120, and a further component at the rear end of the assembly which is biased rearwardly by a spring 156.

Beyond this, however, a person of ordinary skill in this art would be lost, for the following reasons:

The Examiner suggests that spring 156 of BERGENS et al. acts between the plunger and the syringe. This is a misunderstanding arising from the way in which spring 156 is drawn in Figures 1A and 1B. In Figures 1A and 1B, which are part section views, the spring 156 is visible and so perhaps the Examiner has assumed that the spring is on the central axis of the device, concentric with and in line with the plunger 126. However, it is apparent that the draftsman has

followed the convention of showing the device in part section with the important de-latching mechanism visible even though it is not actually located on the center plane of the device. To further emphasize this, it will be seen in Figures 1A and 1B that the enlarged head of the plunger 126 that acts on the piston 125 in the syringe is visible just to the right of the spring 156. Inspection of Figure 1C makes it absolutely clear that plunger 126 is solid along its whole length from the enlarged head at the right end through to the connection to the piston 125, and so the spring is entirely separate.

The description in Bergens et al is made even more difficult to follow because, in the description, both items 126 and 151 are described as "plungers". Item 126 is variously described as "a plunger 126" (column 11, line 63); "syringe piston 126" (column 12, line 45); "plunger 126" (column 12, line 53; "container plunger 126" (column 13, line 11); "exposed rear plunger 126 part" (column 13, line 19). Item 151 is referred to as a "sleeve-shaped syringe plunger part 151" (column 12, line 24) and elsewhere as a "syringe plunger 151". Attempting to make technical sense of the specification, it is clear that there are two distinct parts namely an item 151 which is of sleeve-form which engages the finger grip 124 of the syringe to move the syringe bodily forward and a separate plunger 126 that is designed to move relative to item 151 that usually would be referred to as the syringe plunger.

The main difficulty with the understanding of Bergens et al is in relation to the "penetration head aggregate" 150. We think there has been some mis-referencing in the drawing and indeed it appears to make more sense reading the words in isolation from the drawings!

The penetration head aggregate comprises a front generally sleeve shaped part 151 having a front surface 152 arranged to contact the syringe. A rear plunger guide 153 having a front end extending into the sleeve-shaped part 151 has a rear end 155 extending well behind the sleeve-shaped part 151. In other words, item 151 is an outer cylindrical sleeve and the rear plunger guide 153 is received inside item 151 and has a rear end spaced rearwardly of 151. A compression damper spring 156 is arranged to bias item 153 rearwardly. (See column 12, lines 22 to 32). The sleeve-shaped part 151 has tapered surfaces 161 at its rear end arranged to compress the legs 143 of the injection head (column 12, lines 40 to 46). The tapering surfaces 161 only become active when the plunger guide 153 moves forward relative to the syringe plunger 151 against the force of the compression spring 156 (column 13 lines 4 to 9). In the initial state (Figure 1A) the legs 143 of the injection head 142 act on the plunger guide 153 (column 12, lines 42, 43). When the drive mechanism is actuated, the injection head 142 acts on the plunger guide 153 which transmits this force through the damping spring 156 to the cylindrical syringe plunger 151 to move the syringe bodily forwards. When the container reaches its forwardmost position the cylindrical syringe plunger 151 ceases further forward movement but the plunger guide 153 continues to move forwardly, against the bias of the compression damping spring 156 so that the tapered surfaces 161 on the outer cylindrical syringe plunger 151 are now exposed and this squeezes the legs 143 of the injection head inwards so that the arms 143 can pass into the interior of both the (outer) cylindrical plunger 151 and the inside of the plunger guide 153. It is only at this point (Figure 1C) that the injection head 143, makes contact with the rear end of the (proper) syringe plunger 126 for the first time.

Accordingly, the second spring 156 in Bergens et al does not act between the syringe plunger and the syringe. The damping spring 156 acts in a load path between the main injection spring and the syringe but it never acts between the syringe and the syringe plunger.

The Examiner cites various passages of Bergens et al which refer to the possibility of applying damping during the auto-penetration movement or auto-injection. However, there is no disclosure of a second spring that acts between the plunger and the syringe and which serves to retain the syringe seated at its forward position and ensures that the syringe piston is not acted upon until the needle has penetrated. As is apparent from the later passages cited by the Examiner, the arrangement of Figures 1A to 1C of Bergens et al. requires there to be some form of unlatching auto-injection head which initially applies thrust to the syringe body and thereafter applies thrust to the syringe plunger. There is no teaching of a provision of a second spring to delay the expulsion of the dose until after the syringe has penetrated.

Thus, there is no teaching in Bergens et al. of a spring which acts in compression between the syringe plunger and the syringe. Nor is there disclosure of an arrangement in which, once the syringe reaches its forward position, the first spring compresses a second spring to urge the plunger forward (relative to the syringe) to expel a dose, such that the syringe piston is not acted upon until the needle has penetrated.

In Bergens et al., pre-dribble is not an issue because they avoid the problem by use of a mechanical decoupling operation. It would be nonsensical in such an arrangement (where pre-dribble is already taken care of) to interpose a spring acting between the syringe and the plunger because this would counteract the force applied to the plunger.

In short, a principal distinction between the present invention and Bergens et al. is that, in the arrangement of the present invention, both springs 4 and 5 act on the syringe plunger whereas in the arrangement of U.S. '479 the spring 156, which the Examiner equates to our second spring, never acts on the syringe plunger. In other words, a distinctive feature of the inventive arrangement is that, when the plunger 8 is in contact with the piston 14, the plunger 8 is acted on in opposite senses by the first spring 4 and the second spring 5.

Add to this the fact that, for the reasons given above, a person of ordinary skill in the art would not be taught, by Bergens et al., how to make an operative device in the first place, and it will be seen that Bergens et al. not only does not teach what we claim, but also could not be used by a person of ordinary skill in this art for any useful purpose whatsoever, because its disclosure is incomprehensible.

For any or all of these reasons, therefore, it is apparent that the rejections appealed from cannot stand, but must instead be reversed, and such is respectfully requested.

The claims involved in the appeal are set forth in the Claims Appendix.

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No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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Enclosures: Claims Appendix

(viii) **Claims Appendix**

The claims on appeal:

1. An injection device having a housing with a spring drive operable, firstly to urge a syringe within the housing forwards to a forward position to project its needle from the forward end of the housing and then to press a piston within the syringe forwards to eject a dose through the needle, wherein the spring drive includes a first spring that acts between the housing and a plunger aligned to cooperate with the piston to urge the plunger forwardly and a second spring that acts in compression between the plunger and the syringe in opposition to the first spring when the plunger presses said piston forwards to eject the dose, the second spring being weaker than the first spring but being sufficiently stiff to be in an expanded state when the syringe reaches its forward position with its needle penetrating the flesh of a patient, whereupon the first spring, as it fully expands, will then compress the second spring to urge the plunger forwards and thereby move the piston and expel the dose within the syringe, the second spring meanwhile serving to retain the syringe seated at its forward position.

2. An injection device according to claim 1, wherein the plunger has a collar slidable lengthwise within limits, and the second spring bears on the rear side of this collar, while the forward side of the collar co-operated with the syringe.

3. An injection device according to claim 1, including a third, light spring urging the syringe rearwardly so that its needle is retracted within the housing prior to use.

4. An injection device according to claim 3, wherein the third spring encircles the syringe and acts between a rear flange of the syringe and an internal shoulder of the housing.

5-6. (canceled)

7. An injection device according to claim 2, including a third, light spring urging the syringe rearwardly so that its needle is retracted within the housing prior to use.

8. An injection device according to claim 7, wherein the third spring encircles the syringe and acts between a rear flange of the syringe and an internal shoulder of the housing.

(ix) **Evidence Appendix**

None.

(x) **Related Proceedings Appendix**

None.